12.0 Appendix 2

Drug Shortage Prevention and Response Plan

Risk Triage Approach for Proactive Management of Drug Shortage

(Template is part of TR-68 (Revised), © 2024 PDA, Inc.)

Complete this triage model for each dosage form by assessing the product categorization, the impact of the shortage on patients, and the end-to-end controls used to prevent or mitigate the risk. Use the form proactively to identify ways to prevent a shortage or reactively to respond to a shortage.

A. Basic Data

API name		Drug Product Name	
Pharmaceutical Form and Strengths		ATC (Anatomical Therapeutic Chemical) Code	
Pack Size(s)		Therapeutic Indication(s)	
Route(s) of Administration		Contact Person/Contact Information	
Other Information[1]			

[1] Other information available may include, for example, countries where marketed, reference to market authorization; in case of response plan: affected by the supply disruption, shortage details including impacted countries, expected end date.

B. Impact to Patient

Mark the Risk Level as **A**, **B**, or **C** based on the product's therapeutic use and availability of alternative therapies using the criteria below.

			Availability of Alternatives		
			No Alternatives Available	Alternative Products Available/API Available	Same Product/API Available
Therapeutic Use & Consequences if Alternate Product not Available	Medically necessary product, life supporting or life sustaining	Fatal or severe irreversible harm if the patient is not treated with the product	Risk Level A	Risk Level A	Risk Level B
	Acute short term or chronic long term	Severe harm but reversible if patient is not treated with the product	Risk Level A	Risk Level B	Risk Level C
	Other indications	Inconvenience if patient is not treated with the product	Risk Level B	Risk Level C	Risk Level C

C. Risk Priority Level (1, 2, or 3) Based on Likelihood of a Shortage

Based on the Risk Level (A, B, or C) identified in **Section B,** the probability of a shortage, and the consideration of the drug shortage prevention controls currently in place and their likely effectiveness, indicate the Risk Priority Level (1, 2, or 3) using the criteria below.

		Likelihood of Shortage		
		High	Medium	Low
Therapeutic Use & Consequences if Product not Available	Risk Level A	Risk Priority Level 1	Risk Priority Level 1	Risk Priority Level 2
	Risk Level B	Risk Priority Level 1	Risk Priority Level 2	Risk Priority Level 3
	Risk Level C	Risk Priority Level 2	Risk Priority Level 3	Risk Priority Level 3

D. Risk Control Activities for a Proactive Drug Shortage Prevention Plan

Based on the potential Risk Priority Level (1, 2, or 3), describe suggested controls to be established, the communication plan (in the event of a shortage), and other considerations. This can be done either in text or table form. See a potential table format below.

Risk Priority	Suggested Controls / Preventive Actions
Level 1	…
Level 2	…
Level 3	Generally accepted risk level

E. Risk control Activities for a Drug shortage Response Plan

Develop a drug shortage response plan for implementation in the event of a drug shortage and discuss the plan, as needed, with the relevant health authorities.

1. Identify the reason(s) for the shortage or temporary disruptions (check all that apply):
   - Manufacturing Issues
     - ☐ Industry, e.g., capability, capacity, storage, transport/distribution/shipment, regulatory and quality compliance, CDMO
     - ☐ Component, e.g., raw materials, API, excipient, equipment
     - ☐ Government, e.g., changes in legislation or guidance, enforcement, intellectual property rights protection
     - ☐ Multistakeholder, e.g., infrastructure (e.g., power supply), registration process
     - ☐ Time to manufacture and batch release

- Business Issues
  - ☐ Unexpected product demand
  - ☐ Industry, e.g., quotas
  - ☐ Regulatory delay
  - ☐ Wholesale, distribution, e.g., parallel trade, demand, known real manufacturer
  - ☐ Government, e.g., national protectionism, export ban, health economics, channel strategies
  - ☐ Multistakeholder, e.g., commercial priorities, stockpiling, number of competitors
- Economic and Geographic Issues
  - ☐ Industry, e.g., market withdrawals, delayed introduction
  - ☐ Wholesale, distribution, e.g., commercial tendering
  - ☐ Governments, e.g., price reductions, tax structure, reference pricing, reductions in spending
  - ☐ Multistakeholder, e.g., exchange rate, tightening of payment, payment delay, affordability
- Reliability Issues
  - ☐ Wholesale, distribution, healthcare provider, e.g., off-label use, compassionate use, competitor sourcing
  - ☐ Governments, e.g., environmental standards
  - ☐ Multistakeholder, e.g., competent staff, illegal product introduction, theft, stolen material, counterfeits, substandard, national disasters, health emergencies, pandemic, demand increase
- Others, please specify _____

2. Assess risks to patients from the shortage per **Section B** (attach risk assessment), including the expected duration of the situation and the patient groups likely to be affected by the shortage (e.g., neonates, people with diabetes).

3. Create (and attach) a short-term action plan, based on **Section D** and/or discussions with relevant health authorities, to include actions that can be taken to address the shortage in the near term (e.g., when alternative therapies are available).

4. Execute the communication plan based on the shortage's characteristics (e.g., Dear Health Care Provider letters, informed consent forms, or patient letters)

5. Create (and attach) a longer-term action plan based on **Section D** above, including actions and timelines needed to return the product supply to normal.

F. Risk Review and Updates

Identify the triggers for reviewing and updating the Drug Shortage Prevention and Response Plan.

Check the trigger(s) that will drive reviews and revisions of the Drug Shortage Prevention and Response Plan:

- ☐ New product indication
- ☐ New market approval
- ☐ Approval of a new alternative or unlicensed product
- ☐ Shortage of an alternate product
- ☐ New risks to product quality or availability
- ☐ Shutdown of a facility or withdrawal of GMP Certificate
- ☐ Inventory or safety stock levels below target level
- ☐ Increase in product usage volumes
- ☐ Others, please specify _____

G. Approvals Required

Name	Title and Function	Signature	Date
	Person Responsible		
	QA Decision-Maker		
	Senior Management Function		